AGENDA AND PUBLIC NOTICE

Department of Human Services Institutional Review Board (DHS IRB) Meeting, June 11, 2003, Conference Room 210, 9 a.m

HIPAA ADDENDUMS FOR REVIEW

- Lisa Cannon Albright, Ph.D., IHC Hospital/Genetic Research, Mapping an Osteoporosis Susceptibility Gene in Utah Families, DHS IRB # 980046, Change request to comply with HIPAA, DHS affiliated agency is the Division of Aging and Adult Services (DAAS).
- Lisa Cannon Albright, Ph.D., IHC Hospital/Genetic Research, Mapping Depression Susceptibility Genes in Utah Families, DHS IRB # 970038, Change request to comply with HIPAA, DHS affiliated agency is the Division of Substance Abuse and Mental Health (DSAMH).
- Lisa Cannon Albright, Ph.D./Peter Haug, M.D., IHC Hospital/Genetic Research, Psychiatric Morbidity and Patterns of Co-Morbidity in Utah, DHS IRB # 000120, Change request to comply with HIPAA, DHS affiliated agency is DSAMH.

PROTOCOLS FOR REVIEW

•	Michael Stevens, M.D., Valley Mental Health (VMH), F1D-US-HGLF: Efficacy
	of High Dos Olanzapine in a Controlled Fixed Dose-Response Trial for the
	<u>Treatment of Schizophrenia</u> , DHS IRB # 030226, New Research , DHS affiliated
	agency is DSAMH. RISK LEVEL: \square < Minimal risk; \square Minimal Risk; \square >
	Minimal risk but with direct benefit to subjects; $\square > $ Minimal risk but no direct
	benefit to subjects.
•	Catherine Carter, Ph.D. VMH, Supporting Employment through Personal
	Assistant Services for People with Psychiatric Disabilities, DHS IRB # 030230,
	New Research, DHS affiliated agency is DSAMH. RISK LEVEL:
	Minimal risk; Minimal Risk; Minimal risk but with direct benefit to
	subjects; > Minimal risk but no direct benefit to subjects.
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NOTICE OF SERIOUS ADVERSE EVENTS (SAEs):

Michael Stevens, MD, Valley Mental Health (VMH), <u>CATIE Study</u>, DHS IRB # 000127, Not Locally Occurring SAE, Patient # 0384 CPS, SAE LOG # VMH03-14A. This is a follow-up report on a previously reported SAE that was already reviewed by Dr. Spencer. The follow-up report was FAXed to Dr. Spencer on May 29, 2003.

NOTICE OF EXPEDITED REVIEWS:

•	Jerome Soller, Ph.D., CogniTech Corporation, <u>Utilization of Mental Health</u>
	Scales in Various Mental Health Settings, DHS IRB # 030227, New Research,
	DHS affiliated agency is DSAMH. RISK LEVEL: ⊠ < Minimal risk; □
	Minimal Risk; > Minimal risk but with direct benefit to subjects; >
	Minimal risk but no direct benefit to subjects. Dennis Geertsen and Mary Caputo
	conducted an expedited review of this less than minimal risk study on May 23,
	2003. The research proposes to conduct an anonymous survey of one VMH
	counselor (either MD, SW, etc.) regarding MH scales currently being used. The
	protocol proposes to reimburse the agency (VMH), not the counselor for the
	equivalent of one therapy session. Mary wrote an approval letter on the same date
	for Mark's signature.
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	Caren Frost, Ph.D., M.P.H., University of Utah, College of Social Work,
	Perceptions of Family Court Judges, Guardians ad Litem, and Attorneys General
	of Current DCFS Practice – a Final Follow-Up Study, DHS IRB # 030229, New
	Research, DHS affiliated agency is DCFS. RISK LEVEL: \boxtimes < Minimal risk;
	Minimal Risk; ☐ > Minimal risk but with direct benefit to subjects; ☐ >
	Minimal risk but no direct benefit to subjects. Navina and Mary did an expedited
	review of the protocol on May 23, 2003, which is a follow-up of a previously
	reviewed and approved study to survey professionals about their perceptions of
	the current DCFS practice. Navina and Mary determined it was less than minimal
	risk and may be conditionally approved pending verification of U of U IRB
	approval, and changing Richard Anderson's title from "Acting Director" to
	"Director" on the survey transmittal memo. Mary prepared a conditional approval
	letter for Mark Ward's signature.
•	Caren Frost, Ph.D., M.P.H., University of Utah, College of Social Work,
	Employee Perception Survey, DHS IRB # 030228, New Research, DHS
	affiliated agency is DCFS. RISK LEVEL: ⊠ < Minimal risk; ☐ Minimal Risk;
	☐ > Minimal risk but with direct benefit to subjects; ☐ > Minimal risk but no
	direct benefit to subjects. Minimal risk but no direct benefit to subjects. Navina
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	pending verification of U of U IRB approval, and changing Richard Anderson's
	title from "Acting Director" to "Director" on the survey transmittal memo. Mary
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